



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,326	09/24/2003	Donald J. Kyle	1861.1640001/JMC/THN	2306
26111	7590	04/14/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC			AULAKH, CHARANJIT	
1100 NEW YORK AVENUE, N.W.			ART UNIT	
WASHINGTON, DC 20005			PAPER NUMBER	

1625

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/668,326

Applicant(s)

KYLE, DONALD J.

Examiner

Charanjit S. Aulakh

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7 is/are allowed.
- 6) ☒ Claim(s) 8-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

1. Claims 1-11 are pending in the application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 8-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating pain, does not reasonably provide enablement for preventing or ameliorating pain and treating disorders responsive to the excitation of mu opioid receptors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The following eight different factors (see *Ex parte Foreman*, 230 USPQ at 547 ; *Wands, In re*, 858. F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on at least four of the above mentioned eight factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence of working examples and the state of the prior art.

Art Unit: 1625

The instant compounds are mu opioid receptor agonists as demonstrated by in vitro and in vivo data (see table 1) on page 19 and therefore, will have utility in treating but not preventing disease conditions where mu opioid receptor agonists are known in the prior art to have therapeutic benefit effect such as treating pain. The etiology of chronic pain or neuropathic pain is unclear and can be mediated by multiple mechanisms as mentioned in the specification on page 5, second paragraph. There is no teaching either in the specification or prior art that mu opioid receptor agonists will prevent or ameliorate (completely cure) any kind of pain, specially pain in cancer patients and diabetic neuropathy etc. irrespective of the mechanism responsible for the etiology of pain. There are no working examples present to show the effectiveness of the instant compounds in preventing/ameliorating pain in all known animal models of pain. There is no teaching regarding various disorders which are responsive to the excitation of mu opioid receptors or where a mammal is suffering from hypoactivity of mu opioid receptors. In absence of such teachings, guidance and presence of working examples, it would require undue experimentation to demonstrate the effectiveness of the instant compounds in preventing/ameliorating pain and treating all known/unknown disorders responsive to excitation of mu opioid receptors.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1625

5. Claims 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 8, the term ---disorder responsive to excitation of mu opioid receptors---- is indefinite since the disorders are not defined and furthermore, steps for assessing responsiveness to the excitation of mu opioid receptors are not defined.

In claims 9-11, the terms --- preventing and ameliorating--- are indefinite since the degree of prevention or amelioration such as 20%, 50%, 70% or 100% are not defined.

Allowable Subject Matter

6. The following is a statement of reasons for the indication of allowable subject matter:

The instant compounds of formula I, pharmaceutical compositions containing these compounds and a method of treating pain using these compounds are allowable over the prior art since they are neither disclosed nor obvious over the prior art. In the prior art, Iorio (Eur. J. Med. Chem., cited on applicants form 1449) discloses compounds of formulae 1b and 2b on page 301 which are closely related to instant compounds.

However, the compounds of Iorio differ from the instant compounds in having hydroxyl group instead of hydrogen in the 9th position and furthermore, there is no teaching, suggestion or motivation in the prior art to modify the compounds of Iorio to prepare the instant compounds having agonist activity at mu opioid receptors.

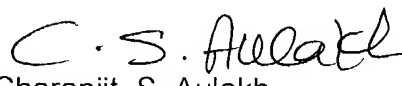
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is

Art Unit: 1625

(571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Charanjit S. Aulakh
Primary Examiner
Art Unit 1625